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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,767	05/04/2001	Kun Chen	301505.2003-001	6656
207	7590	10/18/2006	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			LAURITZEN, AMANDA L	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,767	Applicant(s) CHEN ET AL.	
	Examiner Amanda L. Lauritzen	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 Jul 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7/10/2006 have been fully considered but they are not persuasive.

1. Rejection of claims 11 and 36 under 35 U.S.C. 112, first paragraph, for failure to comply with the enablement requirement is sustained. The passages referenced to in the specification are directed to the method of acquiring data and subsequent processing for image generation and are not specific to method steps or a process of measuring the size of a tumor or lesion.

Furthermore, the millimeter tick marks on the graphical image displays of Figs. 5A-D, 6A-D and 9A-D present no novel means for determining the size of an object displayed in an image.

2. Rejection of claim 40 under 35 U.S.C. 112, second paragraph, is sustained. The statement "the light distribution function defines a plurality of light paths having a cross-sectional area, the area being less than diffusion approximation of the area" is not clear even in light of the specification.

3. With regard to the light distribution function of Chernomordik, the scaling factor applied is a function of the scattering component, as is cited in applicant's claims 1 and 12. Furthermore, the reference cites in the right column of p. 1858 that in providing a light distribution function, "any imaging process can be represented as a product of transmission and reception directivity patterns" which include both scattering and absorption components.

4. With regard to applicant's statement of there being no indication of the references measuring the size of objects such as tumors in the medium, the imaging methods described in all references cited are applicable for noninvasive detection of tumors, which includes determination of the size and location of a tumor embedded in tissue.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The amendments to claims 1, 12 and 26 directed at measuring the size of an object within the medium are rejected for the same reasons cited with regard to claims 11 and 36 in section 1 above. There is no mention in the specification as to the method steps or the process for determining the size of an object or lesion in the medium.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The statement “the light distribution function defines a plurality of light paths having a cross-sectional area, the area being less than diffusion approximation of the area” is unclear. It is not possible to determine what the applicant is claiming.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 9, 11-13, 22, 26-29, 34, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chernomordik, et al (“Point spread functions of photons in time-resolved transillumination experiments using simple scaling arguments”). Chernomordik discloses a method of imaging in which near-infrared radiation, which is approximately between 750 and 3000 nm, is used to image inside an optically turbid slab. The point spread function used is valid at short times and takes into account both scattering and absorption and is valid at short times, “which should be applicable to the analysis of transport through slabs whose thickness is but a few times the inverse of the transport-corrected mean-free path” (pg 1857). A plurality of light distribution functions are used, as the PSF of “any imaging process can be represented as a product of transmission and reception directivity patterns” (page 1858). It is inherent in the disclosure that a light source, a detector, and a data processor connected to the detector would be used in order to obtain the data shown in the figures and that an image is formed from the disclosed image reconstruction algorithms. The imaging allows for the noninvasive detection of tumors, which are embedded in tissue (pg 1857) to allow determination of the size and location of a tumor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-8, 15, 17-21, 23, 31, 32, 37, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winn, et al (“Distribution of the paths of early-arriving photons traversing a turbid medium”). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to explicitly disclose the structural elements used with the light distribution function. Winn also discloses a system and method for optical tomographic imaging in a turbid medium and provides details as to the structural elements used. Winn discloses using a laser to generate the light used, collected with a bundle of optical fibers, and detected by a streak camera detection system (pg 8086), which may be aligned with each other when Δx is set to 0 (pg 8090). The “beam and detectors sweep together horizontally along the tank, and the photon intensity $I(t)$ is recorded at each position x ” (pg 8090), which provides relative movement between the object being imaged and the sensor. The detection system is gated by control units (pg 8086). The pulses of the laser light have a duration of 150 fs. It is noted that, “the width of the spatial distribution of paths of early-arriving photons is substantially narrower than that for highly diffused photons” (pg 8085). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik with the teachings from the reference by Winn, as the reference discloses an improved system and methods for optical computed tomography to obtain “distribution photon paths in a turbid medium for short times of flight” (pg 8086).

9. Claims 5, 16, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chernomordik in view of Chang, et al (US 5454047). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to disclose using a light distribution function including a series expansion. Chang discloses an

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optical method for an image processing function in which a series expansion of a function is used, “the expansion coefficients thus generated may be used to recreate the image as with a Fourier series approach” (col 1, lines 50-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik and include a series expansion in the light distribution used by Chernomordik for image processing as “the advantage is that fewer terms are required to effectively recreate an image” (col 1, line 60) thereby decreasing processing time and memory space requirements.

10. Claims 10, 14, 25, 35, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chernomordik in view of Barbour, et al (“Imaging of Subsurface Regions of Random Media by Remote Sensing”). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to disclose providing a plurality of weighting functions. Barbour also discloses a method for generating optical images of tissue that takes into account both absorption and scattering properties of tissue (pg 192). A weighting function is used to give a weight to each voxel (pg. 196) as well as computing weight functions for all source-detector configurations in order to localize inhomogeneities in 3D space (pg 198), which are displayed as images (figure 4). Barbour also teaches that the problem may employ “a reciprocity theorem of radiation transport theory” (pg. 194). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik with the teachings from the reference by Barbour, as it takes into account both absorption and scattering properties of tissue (pg. 197) and provides that images in “successively deeper regions” may be obtained using this method as compared with other optical tomography methods.

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11. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita, et al (US 6240309). Chernomordik, as discussed above, discloses a method of imaging an object using a light distribution function, however fails to disclose using an internal probe to obtain images of the tissue. Yamashita discloses an optical measurement instrument in which a probe is used for optical computed tomography by “effecting tomography on an inner living body with light is image-processed by a computer” (col. 12, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Chernomordik with the teachings from the reference by Yamashita, as using a probe internally as well as externally would provide greater flexibility for the system and images could be obtained for tissue that is well below the skin’s surface.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chance (U.S. Publication No. 2005/0197583) in which tumor size is indicated by a 2D optical projection image (para. 0140, lines 9-11; refer also to Figs. 10-13 for tick-mark scaled images of abnormal tissue that will permit measurement of specific structures).

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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